

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ASTRAZENECA PHARMACEUTICALS LP,)	
ASTRAZENECA UK LIMITED,)	
IPR PHARMACEUTICALS, INC., and)	
SHIONOGI SEIYAKU KABUSHIKI KAISHA,)	
)	
Plaintiffs,)	C.A. No. 07-809-JJF
)	
v.)	
)	
APOTEX INC., and APOTEX CORP.,)	
)	
Defendants.)	

**DEFENDANT APOTEX INC.'S BRIEF IN SUPPORT OF ITS RULE 12(B)(2) MOTION
TO DISMISS FOR LACK OF PERSONAL JURISDICTION OR IN THE
ALTERNATIVE TO TRANSFER TO THE MIDDLE DISTRICT OF FLORIDA**

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Dated: January 31, 2008
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I. NATURE AND STAGE OF PROCEEDINGS

This is an action for patent infringement brought pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355(j). Plaintiffs AstraZeneca Pharmaceuticals, LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc. and Shionogi Seiyaku Kabushiki Kaisha ("Plaintiffs") claim that they own all substantial rights in U.S. patent no. RE37,314 ("314 patent) covering the drug rosuvastatin calcium, which is used to treat high cholesterol, and is sold under the brand name CRESTOR®. Defendant Apotex Inc. is a Canadian Corporation that filed an Abbreviated New Drug Application ("ANDA") under 21 U.S.C. § 355(j)(2)(A), claiming that the '314 patent is invalid.

Plaintiffs' complaint alleges, pursuant to 35 U.S.C. § 271(e)(2)(A), that Apotex Inc. has infringed the '314 patent by submitting the ANDA for rosuvastatin calcium tablets. The Complaint was filed on December 11, 2007. (D.I. 1.) Apotex Inc. was given until January 31, 2008 to answer or otherwise plead. (D.I. 8.)

II. SUMMARY OF ARGUMENT

This Court lacks personal jurisdiction over Apotex Inc. because Apotex Inc. has insufficient contacts with Delaware to satisfy the state's long-arm statute or the requirements of due process. Apotex Inc. is a Canadian company with its headquarters in Canada. It has no offices, property, or employees in Delaware and sells no product in Delaware. Apotex Inc. has no subsidiary in Delaware and no contracts with any Delaware individuals or entities. Case law is clear that under such circumstances, there is no personal jurisdiction.

In the alternative, Apotex Inc. requests that this matter be transferred to the Middle District of Florida under 28 U.S.C. § 1631, where Apotex Inc. has filed a declaratory judgment complaint against Plaintiffs in a related proceeding based on the same ANDA at issue in this

case. A transfer is appropriate because Apotex Inc.'s designated U.S. agent for purposes of the ANDA is located in Florida and Apotex Inc. agrees to submit to personal jurisdiction there.

III. STATEMENT OF FACTS

Apotex Inc. is a Canadian Corporation that manufactures and sells generic drugs, and has its headquarters in Toronto, Ontario, Canada. (Declaration of Bernice Tao ("Tao Dec.") par. 1, Exhibit A.) Apotex Inc. has never sold any product in the State of Delaware, and has no offices, facilities, telephone listings, bank accounts, or real property in Delaware. The company has no employees in Delaware and does not solicit business in Delaware. (*Id.* pars. 4-8.) Apotex Inc. does not have any subsidiaries located in Delaware and has no contracts with any individuals or entities in Delaware. Apotex Inc. is not registered with the Secretary of State to do business in Delaware and is not licensed by the State of Delaware to sell drugs in the state. (*Id.* pars. 3, 7.)

Apotex Inc. submitted Abbreviated New Drug Application ("ANDA") No. 79-145 to the FDA for a proposed drug product consisting of rosuvastatin calcium tablets. This ANDA and all supporting materials therefor were prepared by Apotex Inc. employees in Canada. (Tao Dec. par. 9.)

Apotex Inc. has filed a suit for declaratory judgment against AstraZeneca Pharmaceuticals LP, Astrazeneca UK Limited, and IPR Pharmaceuticals, Inc., in the Middle District of Florida, Case No. 8:08-CV-00213-T-30TGW. The Florida case is based on the same ANDA at issue in this case, and involves a different patent—U.S. Patent No. 6,316,460 ("460 Patent"). Apotex Inc. sued for declaratory judgment in connection with the '460 patent because the patent is listed in the Orange Book for rosuvastatin calcium tablets, yet neither the patent owner (AstraZeneca Pharmaceuticals) nor the NDA holder for this drug (IPR Pharmaceuticals) sued Apotex Inc. within 45 days of receiving Apotex Inc.'s letter notifying AstraZeneca of

Apotex Inc.'s ANDA. Consequently, Apotex Inc. sued for declaratory relief as contemplated by 21 U.S.C. § 355(j)(5)(C)(i).

IV. ARGUMENT

In order for this Court to exercise personal jurisdiction over Apotex Inc., this Court must engage in a two-part test. It must first determine whether there is a statutory basis for finding jurisdiction under the Delaware long-arm statute, 10 Del. C. § 3104(c). *Merck & Co., Inc. v. Barr Laboratories, Inc.*, 179 2d 368, 371 (D. Del. 2002). Secondly, the Court must determine if an exercise of jurisdiction violates Defendant's constitutional right to due process. *Id.*, citing *International Shoe Co. v. Washington*, 326 U.S. 310 (1945).

Once a jurisdictional defense has been raised, Plaintiffs bear the burden of establishing with reasonable particularity that sufficient minimum contacts have occurred between Defendants and Delaware to support jurisdiction, and to satisfy this burden, Plaintiffs must establish either specific or general jurisdiction. *Merck*, 179 at 371. "Specific jurisdiction arises when the particular cause of action arose from the defendant's activities within the forum state; general jurisdiction arises when the defendant has continuous and systematic contacts with the state, irrespective of whether the defendant's connections are related to the particular cause of action." *Id.* As will be shown below, Plaintiffs have failed to satisfy their burden of establishing either type of jurisdiction, and have failed to establish facts that satisfy the requirements of due process.

A. PLAINTIFFS HAVE NOT ESTABLISHED SPECIFIC JURISDICTION

Plaintiffs cannot prove specific jurisdiction because the cause of action at issue here did not arise from Defendant's activities within the State of Delaware. The claim of patent infringement is based solely upon Apotex Inc.'s filing of and Abbreviated New Drug Application

with the FDA, as set forth in 35 U.S.C. § 271(e)(2)(A). Consequently, this Court must examine the facts surrounding Apotex Inc.'s preparation and filing of its ANDA. The ANDA itself and all supporting materials were prepared in Canada (Tao Dec. par. 9), and the ANDA was filed with the FDA in Maryland. There is no substantive connection to Delaware. In fact, the ANDA's only contact with Delaware is the fact that Apotex Inc. mailed notice of the ANDA certification to AstraZeneca in Delaware. Case law is clear, however, that this is not enough to establish specific personal jurisdiction. *Glaxo Inc. v. Genpharm Pharmaceuticals, Inc.*, 796 F. Supp. 872, 876 (E.D.N.C. 1992)("[N]othing in the [ANDA] statute or case law suggests that the defendant would be subject to an infringement suit wherever the [§355(j)(2)(B)(i)] notice to the approved-NDA holder is mailed. Mailing a statutorily-required notice is not akin to soliciting business, introducing products into the forum, or signing and performing a contract within the forum.") Consequently, Plaintiff has not met its burden of establishing specific jurisdiction.

B. PLAINTIFFS HAVE NOT ESTABLISHED GENERAL JURISDICTION

Neither have Plaintiffs carried their burden of establishing general jurisdiction under the Delaware long-arm statute. The general jurisdiction provisions of the Delaware long-arm statute state in relevant part:

(c) As to a cause of action brought by any person arising from any of the acts enumerated in this section, a court may exercise personal jurisdiction over any nonresident, or a personal representative, who in person or through an agent:

(4) Causes tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State.

10 Del. C. § 3104. The relevant inquiry for purpose of this motion is whether Apotex Inc. regularly does or solicits business or engages in any persistent conduct in the State,

or derives substantial revenue from services or things used or consumed in Delaware. 10
 Del. C. § 3104(c)(4). Apotex Inc. has no such contacts.

Apotex Inc. is a Canadian corporation that has no contacts with Delaware—no offices, no real property, no telephone listings, no bank accounts, and no employees. Apotex Inc. does not sell any product in Delaware and does not solicit sales in this state. It is not registered with the Secretary of State to do business in Delaware and is not licensed by the State of Delaware to sell drugs in this State. Apotex Inc. does not have any subsidiaries in Delaware and does not have any contracts with any individuals or entities in Delaware. (Tao Dec. pars. 1-8.)

This utter lack of contacts with Delaware compels the conclusion that general subject matter does not exist under the Delaware long-arm statute. In *Merck & Co., Inc. v. Barr Laboratories, Inc.*, 179 F. Supp. 2d 368, 371 (D. Del. 2002), the plaintiff patent holder, like the Plaintiffs here, brought a suit for patent infringement based on the Defendant's filing of an ANDA. This Court granted Defendant's motion to dismiss for lack of personal jurisdiction, where the Defendant was a foreign corporation with no employees, telephone listings, bank accounts or real estate in Delaware. This Court ruled that the defendant did not have sufficient contacts to establish general jurisdiction under the Delaware long-arm statute because its sales were minimal; its conduct did not amount to regularly doing or soliciting business in Delaware; and the defendant did not derive "substantial revenue" from services or things used or consumed in Delaware:

[T]he Court concludes that Barr's revenue from things used or consumed in Delaware falls below the level required to exercise general jurisdiction. . . . Currently, Barr's Delaware revenue, comprising less than 0.13% of total revenue, is not substantial enough to warrant an exercise of general jurisdiction.

Merck, 179 F. Supp. 2d at 373. The case at bar presents an even stronger case for dismissing Apotex Inc. for lack of subject matter jurisdiction than was present in *Merck*, because Apotex Inc. has absolutely no presence in Delaware—no sales, no employees, no offices or real estate, no license to do business there, no subsidiaries, advertising or marketing, and no direct sales. The Defendant in *Merck*, on the other hand, was licensed by the State of Delaware to sell drugs in the state, it had made some direct sales to customers in the state; it had an account manager who visited Delaware around 3 times per year; and the Defendant had a contract with a Delaware company for the storage and nationwide distribution of product, and a wholly-owned subsidiary for research and development of pharmaceuticals. If, under these facts, this Court concluded that personal jurisdiction was lacking, the case at bar presents an even stronger case for dismissal.

Likewise, in *Glaxo Inc. v. Genpharm Pharmaceuticals*, 796 F. Supp. 872, 875-76 (E.D.N.C. 1992), the court concluded that it lacked personal jurisdiction over a Canadian defendant who filed an ANDA where the defendant did not regularly transact or solicit business in North Carolina; was not licensed to do business there; had never manufactured, sold, marketed or distributed anything in North Carolina; never leased or owned real property there; and never had a North Carolina bank account, mailing address or telephone number. In fact, the defendant's only contact with the forum state (like Apotex Inc. in this case) was the mailing of the ANDA certification of invalidity to plaintiff in North Carolina, and this was not enough to satisfy requirements of long-arm statute or due process. 796 F. Supp. at 876.

Because there is no basis for extending the state's long-arm jurisdiction against Apotex Inc., the Complaint should be dismissed against it for this reason alone. *See also*

Glaxo Wellcome Inc. v. Mylan Pharmaceuticals, Inc., No. AMD 96-3477, 1997 U.S. Dist. LEXIS 23930, at *6-7 (D. Md. March 31, 1997) (granting defendant ANDA filer's motion to dismiss for lack of personal jurisdiction because defendants' contacts were "limited at best"); *Zeneca Limited v. Mylan Pharmaceuticals, Inc.*, No. S 96-1736, 1997 U.S. Dist. LEXIS 12377, at *7-8 (D. Md. Jan. 3, 1997) (no personal jurisdiction over defendant ANDA filer where defendant had limited contacts with the State of Maryland).

In their Complaint, Plaintiffs allege that personal jurisdiction over Apotex Inc. is proper because it "purposefully avails itself of the privilege of selling its generic products in the state of Delaware" and "directly or through its subsidiary Apotex USA, places goods into the stream of commerce for distribution throughout the United States, including the State of Delaware." (Complaint par. 17, D.I. 1.) This argument, however, is unavailing because the "stream of commerce" theory of personal jurisdiction only applies in cases of specific jurisdiction. And, as explained above, there is no basis for alleging specific jurisdiction because the Plaintiffs' alleged basis for personal jurisdiction (Apotex USA's alleged sale of product in Delaware) is not related to the cause of action here (preparing and filing an ANDA for permission to make and sell a product that is not yet on the market). In *Zeneca Limited*, 1997 U.S. Dist. LEXIS 12377, at *12 (D. Md. January 3, 1997), the court rejected the "stream of commerce" theory of personal jurisdiction under similar facts:

Given . . . Supreme Court and Federal Circuit precedent, it is clear that this Court could only exercise specific or "stream of commerce" jurisdiction over the defendant Mylan if the instant action arose out of Mylan's contacts with Maryland, the forum state. . . . [T]he instant action does not arise out of Mylan's contacts with Maryland. As a result, personal jurisdiction over Mylan cannot be maintained by this Court under the 'stream of commerce' theory of specific jurisdiction."

For the same reason, Plaintiffs' stated basis for asserting personal jurisdiction over Apotex Inc. should be rejected.

C. AN EXERCISE OF JURISDICTION HERE WOULD VIOLATE DUE PROCESS

This case should be dismissed for the additional reason that the exercise of personal jurisdiction over Apotex Inc. would violate due process. The issue of personal jurisdiction in a declaratory action for non-infringement is governed by Federal Circuit law regarding due process. *Breckenridge Pharmaceutical, Inc. v. Metabolite Laboratories, Inc.*, 444 F.3d 1356, 1361 (Fed. Cir. 2006). Under the federal due process standard, this Court must inquire "whether the defendant has 'purposefully directed his activities' at the forum state and, if so, whether 'the litigation results from alleged injuries that arise out of or relate to those activities.'" *Id.* at 1361-62, quoting *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985). Again, as explained above, Apotex Inc. has engaged in no activities in the state of Delaware, let alone the required activities relating to the preparation and filing of the ANDA in this case that would satisfy due process. As this Court concluded in *Merck* under less compelling facts:

[T]he Court concludes that the requirements of due process are not satisfied because Barr's business contacts with Delaware and its residents are not continuous and systematic. Barr has not availed itself of Delaware resources in that Barr has no employees, bank accounts, or real estate in Delaware. Barr does not solicit business, through advertising or otherwise, in Delaware. The total revenue Barr derives from Delaware, approximately \$991,000 annually, is less than one percent of Barr's total revenue. Barr has a license to sell pharmaceutical products in Delaware, but is not registered with the Secretary of State to do business in Delaware.

179 F. Supp. 2d at 375. Apotex Inc. has had no contact with Delaware, let alone continuous or systematic contact that would meet the strict requirements of due process.

D. IN THE ALTERNATIVE, THIS CASE SHOULD BE TRANSFERRED TO THE MIDDLE DISTRICT OF FLORIDA

In the alternative, Apotex Inc. moves, pursuant to 28 U.S.C. § 1631, to transfer this case to the Middle District of Florida, where a related case is currently pending between Apotex Inc. and three of the named Plaintiffs in this case. Apotex Inc.'s designated U.S. agent for purposes of this action is located in Florida, and Apotex Inc. consents to jurisdiction in that state for purposes of this case. Consequently, the case should be transferred "in the interest of justice." *Id.* This course of action is commonly taken in ANDA cases where the court determines that it lacks personal jurisdiction over the ANDA filer. *See Glaxo Inc.*, 796 F. Supp. at 877 (transferring ANDA case to District of Maryland where Canadian ANDA filer consented to personal jurisdiction and where the filer maintained a U.S. agent) *Glaxo Wellcome*, 1997 U.S. Dist. LEXIS 23930 at *8 (transferring ANDA case to Eastern District of North Carolina where court lacked personal jurisdiction over ANDA filer); *Zeneca*, 1997 U.S. Dist. LEXIS 12377 at *22 (transferring ANDA case to the Western District of Pennsylvania under Section 1631 after determining the court lacked personal jurisdiction over the ANDA filer)

V. CONCLUSION

For the reasons stated herein, Defendant Apotex Inc. respectfully requests that the Complaint against it be dismissed for lack of personal jurisdiction or, in the alternative, that this case be transferred to the Middle District of Florida.

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Dated: January 31, 2008
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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on January 31, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on January 31, 2008, I have Electronically Mailed the document to the following person(s):

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EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT
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ASTRAZENECA PHARMACEUTICALS LP,
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SHIONOGI SEIYAKU KABUSHIKI
KAISHA,

Plaintiffs,

v.

APOTEX INC.,
And
APOTEX CORP.,

Defendants.

Civil Action No.: 07-809 JJF-LPS

DECLARATION OF BERNICE TAO

BERNICE TAO, of full age, hereby declares as follows:

1. I am Director, Regulatory Affairs U.S. for Apotex Inc., which is a Canadian Corporation with its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L1T9. Apotex Inc. develops and manufactures quality generic pharmaceuticals that are sold throughout the world.

2. I have personal knowledge of the facts set forth herein, or believe them to be true based on information I have received in the course of my duties, and am competent to testify to the same.

3. Apotex Inc. is not registered with the Secretary of State to do business in Delaware and is not licensed by the state of Delaware to sell drugs in and through Delaware.

4. Apotex Inc. does not maintain offices, facilities, local telephone listings, or bank accounts in Delaware.

5. Apotex Inc. has no employees located in Delaware and no Apotex Inc. employees solicit business from individuals or entities located in Delaware.


6. Apotex Inc. does not own or lease any real property or employ any persons in Delaware.

7. Apotex Inc. does not have any subsidiaries located in Delaware, and does not have any contracts with any individuals or entities in Delaware.

8. Apotex Inc. has never directly sold any products in the state of Delaware.

9. Apotex Inc. submitted Abbreviated New Drug Application ("ANDA") No. 79-145 to the FDA for a proposed drug product consisting of rosuvastatin calcium tablets. This ANDA and all supporting materials therefor were prepared by Apotex Inc. employees in Canada.

Pursuant to 28 U.S.C. § 1746(2), I hereby declare under penalty of perjury that the foregoing statements are true and correct.


BERNICE TAO

Executed on: January 31, 2008.